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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,973	10/14/2003	Sheldon B. Moberg	PF00391 CON	9958

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MEDTRONIC MINIMED INC.
18000 DEVONSHIRE STREET
NORTHRIDGE, CA 91325-1219

EXAMINER	
HUH, BENJAMIN	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,973	MOBERG ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/18/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 34, 41-42, & 44-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Das et al (US Patent No. 6423035B1). The Das et al reference discloses an occlusion detection system for detecting an occlusion in a fluid path of an infusion pump with a reservoir containing fluid for delivering fluid to a user in figures 1-9, the occlusion detection system comprising a housing 7, a motor 10 contained within the housing 7, a drive train (seen as elements 20, 21, 18, 28) having a front end and a rear end, the front end of the drive train being operatively coupled to the reservoir 12, and the drive train including at least one drive train component including elements 20 a plunger, 21 a plunger stem, 18 a lead screw, & 28 a gear train, that reacts to a stimulus from the motor to force the fluid from the reservoir into the user, a sensor 16, a force sensor, seen to be positioned on the drive train near the front end of the drive train to measure tension or compression proportional to a pressure applied to the at least one drive train component, and wherein the sensor 16 is fully capable of producing three or

more output levels across a range of measurements due to it's ability to work in the environment; and an electronics system 200 that is fully capable of processing the three or more output levels to declare when an occlusion exists due to it's ability to work in the environment since it has a processor.

With regards to claims 41-42, wherein the at least one drive train component is a cap seen to be element 20 the plunger, which is a cap of the plunger stem 21, wherein the plunger is constructed of a resilient material.

With regards to claim 44 as applied to claim 34, now looking at the element in a different light further including a stopper seen as the element 20 the plunger, slidably positioned in the reservoir to push the fluid out of the reservoir.

With regards to claim 45, wherein the at least one drive train component 21 the plunger stem, presses directly against the stopper 20 in response to a stimulus from the motor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al (US Patent No. 6423035B1) in view of Dixon et al (US Patent No. 3677218). Even though Das et al does not explicitly disclose the use of a bellows with a sensor

attention is directed to Dixon. The Dixon reference discloses a fluid pressure sensor device in figures 4-5 comprising a fluid filled threaded bellows wherein the bellows includes a proximate wall, a distal wall, and a flexible sidewall constructed of a resilient material wherein the sensor is mounted on the distal wall of the bellows, therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Das to incorporate the bellows & sensor of Dixon in order to provide a reliable and precise way to measure the pressure in the line.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al (US Patent No. 6423035B1) as applied to claim 34 and in further view of Tseo (US Patent No. 4747828). Even though Das does not explicitly disclose the use of a strain gauge as the sensor attention is directed to Tseo. The Tseo reference teaches the use of a strain gauge for occlusion detection in figures 3 & 5 also see col. 3 lines 3-12, therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Das to utilize the strain gauge of Tseo in order to provide a reliable and precise way to measure the pressure.

Claims 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Das et al (US Patent No. 6423035B1) in view of Vovan (US Patent No. 6062087). The Das reference discloses an occlusion detection system for detecting an occlusion in a fluid path of an infusion pump with a reservoir containing fluid for delivering fluid to a user in figures 1-9, the occlusion detection system comprising a housing 7, a reservoir

12 containing fluid 14 for delivering fluid to a user, a stopper 20 slidably positioned in the reservoir to push the fluid out of the reservoir, a motor 10 contained within the housing 7, a drive train (seen as elements 20, 21, 18, 28) having a front end and a rear end, the front end of the drive train being operatively coupled to the reservoir 12, and the drive train including at least one drive train component including elements 20 a plunger, 21 a plunger stem, 18 a lead screw, & 28 a gear train, that reacts to a stimulus from the motor to force the fluid from the reservoir into the user, a sensor 16, a force sensor, seen to be positioned on the drive train near the front end of the drive train to measure tension or compression proportional to a pressure applied to the at least one drive train component, and wherein the sensor 16 is fully capable of producing three or more output levels across a range of measurements due to it's ability to work in the environment; and an electronics system 200 that is fully capable of processing the three or more output levels to declare when an occlusion exists due to it's ability to work in the environment since it has a processor. Now, even though the Das reference does not disclose the sensor being in direct contact with the stopper or a cap drive train component attention is directed to Vovan. The Vovan reference discloses a sensor, more specifically a strain gauge 44, being in direct contact with a stopper 30 with a resilient cap support assembly 40 for the sensor, see figure 2 & abstract, therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Das to utilize the strain gauge and cap in contact with the stopper in order to provide a more direct relation between the pressure observed and the pressure perceived by the sensor.

Response to Arguments

Applicant's arguments filed 7/18/06 have been fully considered but they are not persuasive.

Applicant argues that Das does not disclose a sensor positioned on the at least one drive train component at or near the front end of the drive train, the examiner disagrees. The specification of the instant application does not define what "near the front end of the drive train" explicitly is, it is currently the examiner's position that the sensor 16 is deemed to be near the front end of the drive train since the claims do not require for the sensor to be at the very front of the front end of the drive train.

Applicant argues that there is no motivation for providing the sensor in direct contact with a stopper, the examiner disagrees. The applicant even states that in MPEP 2143.01 that the obviousness can be established by suggestion or motivation to do so implicitly in the references or in the knowledge generally available to one of ordinary skill in the art. The motivation of the combination would be to provide the more direct relation between the actual pressures which is suggested by the combination found in Vovan and also known to those of general knowledge in the art that utilizing a pressure sensor directly in conjunction with the parameter to be measured can be advantageous with respect to the fact that there would be a less chance of erroneous perceptions of pressure due to having to relay the pressure to the sensor through various components

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER